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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,816	02/22/2002	Richard Axel	0575/64019-A/JPW/ADM	1776
7590 Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			EXAMINER ULM, JOHN D	
			ART UNIT 1649	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/081,816	AXEL ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	John D. Ulm	1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 January 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 57-73 is/are pending in the application.
- 4a) Of the above claim(s) 63 and 64 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 57-62 65-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

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- 1) Claims 57 to 73 are pending in the instant application
- 2) Claims 63 and 64 stand withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
- 3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 January of 2007 has been entered.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 5) Claims 57 to 62 and 65 to 73 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 57 to 62, 65 to 69, 71 and 72 in section 3 of the office action mailed 13 June of 2005. As stated therein, the instant claims are drawn to an isolated DNA encoding the elected species of protein identified therein as Gr63F1 (SEQ ID NO:12), a putative odorant receptor of insect origin, and the protein encoded thereby, which lack a specific and substantial utility in currently available form because the instant application does not identify a particular compound or class of compounds that activates or inhibit a Gr63F1 protein of

the instant invention nor does it disclose with specificity the consequence of that activation or inhibition.

Applicant has traversed this rejection on the basis that “[t]he value of the invention is dramatically underscored by the Nobel Prize awarded to inventor Richard Axel for the discoveries underlying it”. First, Applicant is advised that Richard Axel did not receive a Nobel Prize for isolating a cDNA encoding an insect odorant receptor. He received a Nobel Prize for a body of work that involved the molecular characterization of the process of sensation and, in particular, the structural and functional characterization of the components involved in the process of olfaction. The molecular characterization of a natural process does not inherently result in the production of a patentable product.

Second, the criteria for winning a Nobel Prize and the criteria for receiving a patent are substantially different. This is why many Nobel Prize recipients do not hold even a single patent and why most patent holders have never won a Nobel Prize.

Applicant’s attention is again direct to the decision *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), which concluded with the statement that:

“This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something ‘useful,’ or that we are blind to the prospect that what now seems without ‘use’ may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy.”

Applicant has further traversed this rejection on the premise “the receptors” encoded by the claimed nucleic acid “can be used to screen for compounds which specifically bind to the receptor”. Whereas one could certainly employ a cell expressing

a receptor of the instant invention in a process of identifying compounds that bind to that receptor, such a process is without practical utility until one knows the nature of the physiological response elicited in an insect by the activation of the particular receptor, such as Gr63F1, that is employed in such a process. Because one of ordinary skill in the art readily appreciates that certain compounds are going to attract insects by binding to one or more specific odorant receptors while other compounds will repel them by binding to one or more different receptors, one can not employ a nucleic acid encoding a Gr63F1 protein of the instant invention in the specific, substantial and practical application of identifying compounds that attract or repel insects until one has first determined what effect the activation of Gr63F1 has on the behavior of an insect. Until one knows if a compound that binds to Gr63F1 is an attractant or a repellent, a process that merely identifies compounds with that activity does not provide an immediate benefit to the public.

Applicant has cited the Kim et al. publication (Chem. Senses 26:195-199, Feb. 2001) essentially in support of the position that "one of ordinary skill in the art would understand that the gustatory receptor Gr63F1 would have a specific, substantial and credible use without knowing the specific compounds that bind to it". The Kim et al. publication describes the characterization of the role of a specific odorant receptor in the olfaction process of the species of fly in which it is naturally produced. This publication shows that one could employ a nucleic acid of the instant invention to discover the physiological relevance of the protein encoded thereby. However, employing a chemical composition as the object of further research does not constitute a practical

utility. It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research such as that described by Kim et al., when that research is needed to establish a specific utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)).

Applicant's assertion that the claimed nucleic acid has utility in the identification of attractant compounds is not supported by the facts of record. As indicated by the text on pages 1, 2 and 20 of the instant specification, one has a reasonable expectation that the activation of a receptor protein of the instant invention by a compound that binds thereto may induce attraction, aversion, feeding, mating or egg laying behavior, depending upon the precise physiological role of that receptor. Because the instant specification leaves it to the artisan to discover which behavior or set of behaviors is effected by the activation of the receptor protein encoded by the claimed nucleic acid, a process that merely employs that receptor protein in the identification of compounds that bind thereto lacks a specific and substantial utility in currently available form.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6) Claims 57 to 62 and 65 to 73 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.
- 7) Applicant's arguments filed 08 January of 2007 have been fully considered but they are not persuasive.

8) This is a continuation of applicant's earlier Application No. 10/081,816. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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